

REMARKS

Entry of the foregoing, reexamination, and further and favorable reconsideration of the subject application, in light of the following remarks, is respectfully requested.

Interview

The undersigned gratefully acknowledges the courtesies extended to herself and Ms. Kathy Baumeister (Registration No. 26,254) by Examiner Wells and Examiner Padmanabhan during the personal interview conducted on February 4, 2003 ("the Interview"). During the Interview, the outstanding claim rejections, the cited publications, and Applicants' invention were discussed. The Interview Summary (Paper No. 12) provided by the Examiner reflects the discussions held, which are elaborated upon below.

Summary

As is correctly reflected in the Final Official Action Summary, Claims 1-50 are pending. Claims 5, 6, 7, 30, 44, 45, and 46 have been withdrawn from consideration. Claims 1-4, 8-29, 31-43, and 47-50 stand rejected. Acknowledgment has been made to a claim for foreign priority under 35 U.S.C. § 119 (a) - (d) or (f), and all certified copies of the priority documents have been received.

By the foregoing amendment, Claim 19 has been canceled. Claim 1 has been amended to include the content of Claim 19. Accordingly, no new matter has been added.

Also, by the foregoing amendment, Claims 2, 9, 18, 20, 27, 41, 43, and 49 have been amended to correct minor, typographical, and/or linguistic errors. Support for these amendments may be found throughout the Specification. Accordingly, no new matter has been added.

The foregoing amendments have been made without prejudice or disclaimer. Applicants reserve the right to file one or more continuing applications directed to the previously-presented subject matter.

Rejections Under 35 U.S.C. § 112, Second Paragraph

1. **"said at least one biologically active agent (A) ..."**

Claims 1, 18, and 27 stand rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite. *See Page 2 of the Final Official Action.* This rejection is respectfully traversed.

Applicants maintain that "said at least one biologically active agent (A)" is neither vague nor indefinite. However, not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, Applicants have amended Claim 1 to specify what "said at least one biologically active agent[s] (A)" may comprise. Specifically, content from former Claim 19 has been added to Claim 1, and Claim 19 has been canceled.

Applicants believe that this amendment has rendered moot the outstanding rejection. *See the Last Line of the Interview Summary.*

2. **"difficulty soluble"**

Claim 18 stands rejected under 35 U.S.C. § 112, second paragraph, as purportedly vague and indefinite due to the phrase "difficulty soluble." This rejection is respectfully traversed.

Not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, Applicants have amended Claim 18 to omit "difficulty soluble."

Applicants believe that this amendment has rendered the outstanding rejection moot. *See Second-to-Last-Line of Interview Summary.*

3. **"derivative"**

Claim 27 stands rejected under 35 U.S.C. § 112, second paragraph, as purportedly vague and indefinite due to the phrase "derivative." This rejection is respectfully traversed.

Not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, Applicants have amended Claim 27 to delete "derivative" and to include "esters thereof," (Support for this amendment may be found at at least ¶ 0068 of the Specification) as agreed at the Interview.

Applicants believe this amendment has rendered moot the outstanding rejection. *See Third-to-Last-Line of Interview Summary.*

4. **Summary**

Applicants maintain that the amendments discussed above, in conjunction with the additional minor, typographical, and/or linguistic error amendments made to Claims 2, 9, 18, 20, 27, 41, 43, and 49 have rendered moot all outstanding 35 U.S.C. § 112, second paragraph, rejections. Applicants respectfully request withdrawal of these rejections.

Rejections Under 35 U.S.C. § 103(a)

1. Legal Requirements for a Proper Obviousness Analysis

Applicants reiterate that when applying 35 U.S.C. § 103, four tenets of patent law MUST be adhered to: (1) the claimed invention must be considered as a whole, (2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination, (3) the references must be viewed without the benefit of impermissible hindsight vision, and (4) a reasonable expectation of success is the standard with which obviousness is determined. *See MPEP § 2141*, citing *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 (Fed. Cir. 1986). To establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. *See MPEP § 2142*.

Important to the resolution of this case is the fact that mere identification of each claimed element in the prior art is NOT sufficient to negate patentability. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Instead, there "must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 536 (Fed. Cir. 1998). Otherwise, sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. *Rouffet*, 149 F.3d at 1357.

2. Claims 1-3, 8-10, 18-24, 26-29, 40-43, and 47-50

Claims 1-3, 8-10, 18-24, 26-29, 40-43, and 47-50 were again rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over European Patent No. 0 268 164 to Lochhead et al. ("Lochhead," inadvertently referred to as "Lockhead" in Applicants last Reply) in view of U.S. Patent No. 6,136,332 to Grollier et al. ("Grollier"). These rejections are respectfully traversed.

Applicants reiterate that there is no motivation to combine the cited publications because the publications are incompatible. It is improper to combine publications where the publications teach away from their combination. *In re Grasselli*, 713 F.2d 731 (Fed. Cir. 1983). Furthermore, even if combined, the combination of publications fail to teach or suggest every element of the invention as claimed. Therefore, the rejection does not meet the requirements for a *prima facie* case of obviousness.

Lochhead relates to stable oil-in-water emulsions containing water, oil, a neutralizing agent, and a lightly crosslinked modified polymer, and to products based on such emulsions. *See Lochhead, Page 2, Lines 28-31*. The modified polymers have a predominant amount of an acrylic acid and a smaller amount of a long chain acrylate monomer and act as a primary emulsifier. *See Lochhead, Page 2, Lines 28-31*.

Grollier relates to substantially non-aqueous, topically-applicable dermatological/pharmaceutical compositions well suited for preventatively and/or curatively therapeutically treating human skin or mucous membranes. The compositions of Grollier contain at least one volatile oil, at least one phenylated silicone oil, and at least one dermatologically and/or pharmaceutically active agent. *See Grollier, Column 2, Lines 7-*

11. The compositions of Grollier create "films" that exhibit very good hold, transfer little, if at all, and migrate little, if at all. *See Grollier, Column 2, Lines 3-6.*

Applicants maintain that Lochhead and Grollier are incompatible. As indicated above, Lochhead pertains to oil-in-water emulsions, whereas the compositions of Grollier are substantially non-aqueous. *See Grollier, Claim 1.* Accordingly, these publications are inapposite and may not properly be combined.

Even assuming that these publications could be properly combined, they fail to disclose all limitations of Applicants' claimed invention. Applicants' invention pertains to oil-in-water emulsions containing at least one biologically active agent that is non-solubilized and micronized, where at least 80% of said micronized particles have diameters from 1-10 microns, and where at least 50% of said particles have diameters of less than 5 microns. Neither Lochhead nor Grollier provide these non-solubilization, micronization, and size limitations of Applicants' claimed invention. In fact, Lochhead states that "oil-in-water emulsions prepared with the modified polymer have a much larger particle size [than conventional oil-in-water emulsions] averaging about 50 microns and are in the range of 10 to 100 microns." *Lochhead, Page 8, Lines 5-7.*

Applicants maintain that a *prima facie* case of obviousness has not been made out because there is no suggestion or motivation to the combine the cited publications. In fact, the two publications are inapposite and teach against combination. Moreover, the publications do not contain all limitations of the rejected claims. Applicants maintain that select elements from Applicants' invention have merely been identified in Lochhead and Grollier, which is insufficient to negate patentability. Accordingly, Applicants respectfully

request withdrawal of the 35 U.S.C. § 103(a) rejections of Claims 1-3, 8-10, 18-24, 26-29, 40-43, and 47-50 over Lockheed in view of Grollier.

3. Claims 1-4, 8-29, 31-43, and 47-50

Claims 1-4, 8-29, 31-43, and 47-50 were again rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over U.S. Patent 5,073,372 to Turner et al. ("Turner") in view of Lockheed in further view of Grollier, U.S. Patent No. 5,882,633 to Pisson et al. ("Pisson"), U.S. Patent No. 5,916,543 to Kaplan ("Kaplan"), U.S. Patent No. 4,486,405 to Klein ("Klein") and U.S. Patent No. 5,980,939 to Kim et al. ("Kim"). These rejections are respectfully traversed.

The deficiencies of Lockheed and Grollier are detailed above. **Applicants reiterate that the emulsions of Turner are of the oil-in-water type, and thus are as incompatible with Grollier as were the emulsions of Lockheed.** Turner requires from about 0.01 % to about 5% of a cationic surfactant. *Turner, Column 5, Lines 30-39*. Applicants' claimed invention does not require such a cationic surfactant. Accordingly, there is no reason why one of skill in the art would look to Turner for guidance. Moreover, because Applicants' claimed invention lacks an "essential component" of Turner, one of skill in the art would have no reasonable expectation of success in arriving at Applicants' claimed invention.

The compositions of Pisson contain three essential elements: an amide, a dibenzoylmethane derivative, and a 1,3,5-triazine derivative. *See Pisson, Column 2, Lines 25-35*. The compositions of Pisson are particularly photostable and are, therefore, effective sunscreens.

The compositions of Pisson require three essential elements which are not required by Applicants' compositions. **Moreover, the compositions of Pisson do *not* contain a biologically active agent, whereas such an agent is essential to Applicants' compositions.**

Because its essential elements are lacking therein, Pisson may not properly be combined with Lockhead, Grollier, and/or Turner. In addition, Pisson teaches away from combining these publications for the same reason — that is, their essential elements differ. Finally, due to this disparity in components, one would not reasonably have expected to succeed in arriving at Applicants' claimed compositions.

The emulsions of Kaplan contain a nonaqueous phase, an aqueous phase, an oil-in-water emulsifier, and a water-in-oil emulsifier. An advantage of the Kaplan emulsions is that they exhibit exceptionally short rub-in times. *See Kaplan, Column 1, Lines 32-41.*

The emulsions of Kaplan do not contain biologically active agents, as do Applicants' compositions. In addition, Kaplan is silent as to the use of an emulsifying system comprising carboxylic acid copolymers.

The emulsions of Kaplan, like the emulsions of Turner, are incompatible with Grollier. The emulsions of Kaplan do not possess the essential elements of Lochhead, Grollier, Turner, or Pisson. Accordingly, these publications may not properly be combined. Even if combined, these publications do not contain all elements of Applicants' compositions. Because of the disparity in essential elements between the publications and the failure of these publications to teach or suggest Applicants' biologically active agents

coupled with an emulsifying system, one of skill would not reasonably expect to successfully obtain Applicants' invention.

The compositions of Klein require a relatively large amount of pigment and a mixture of two alkoxyated surfactants. *See Klein, Abstract*. The compositions of Klein are aqueous, and thus incompatible with Grollier. The compositions of Klein do not contain biologically active agents, as do Applicants' compositions, nor do the compositions of Klein contain the essential elements of the other cited publications.

Based on the deficiencies, Klein may not properly be combined with Lochhead, Grollier, Turner, Pisson, and/or Kaplan. Even if combined, there would not exist all elements of Applicants' compositions nor a reasonable expectation of success in achieving Applicants' compositions which are particularly well-suited for promoting the penetration of biologically active agents to the base of hair follicles.

The compositions of Kim, intended for oral administration, contain a cyclosporin, an oil component, a hydrophilic cosurfactant, and a surfactant. *See Kim, Abstract*. These four components are "essential." *See, Kim Column 6, Lines 16-18, 27-28; Column 7, Lines 46-47; and Column 8, Lines 28-30*. Accordingly, absence of any one of these "essential" elements runs contrary to the teachings of Kim.

Applicants' compositions, like the compositions of Lochhead, Grollier, Turner, Pisson, Kaplan and Klein, fail to contain all four Kim essential elements. This goes against combining Kim as suggested by the Examiner. Moreover, absence of and/or substitution of these four essential elements thwarts any reasonable expectation of success one would have in arriving at Applicants' compositions.

In summary, the compositions of the cited publications (Lochhead, Grollier, Turner, Pisson, Kaplan, Klein, and Kim) require competing essential elements, which makes their combination impermissible. The compositions of the cited publications are directed to different fields than Applicants' compositions — from photostable sunscreens to oral immunosuppressants. Accordingly, one would not look to these seven publications for guidance. If, somehow, one *did* look to these seven publications, he would not have been motivated to modify them as suggested by the Examiner. The Examiner has merely identified elements of Applicants' invention in these publications. This is not sufficient to negate patentability. Even if somehow motivated to combine these publications as suggested, there would be no reasonable expectation of success and such a combination would lack all limitation of Claims 1-4, 8-29, 31-43, and 47-50.

Based on the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejections against Claims 1-4, 8-9, 31-43, and 47-50 over Lochhead, Grollier, Turner, Pisson, Kaplan, Klein, and Kim.

4. Claims 1-4, 8-29, 31-43, and 47-50

Claims 1-4, 8-29, 31-43, and 47-50 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,750,122 to Evans et al. ("Evans") in view of Lochhead in further view of Grollier, Pisson, Klein, and Kim. These rejections are respectfully traversed.

The deficiencies of Lochhead, Grollier, Pisson, Klein, and Kim are discussed above. Evans does not cure these deficiencies.

Evans pertains to compositions useful for treating hair or skin, and contain panthenol and at least one polyalkylene glycol. *See Evans, Column 2, Lines 19-36.* The compositions of Lochhead, Grollier, Pisson, Klein, and Kim do not require panthenol and polyalkylene glycol — making the combination of these publications impermissible. Due to the varied nature of these cited publications, one would not look to the collection of publications relied upon by the Examiner. Moreover, even if combined, this combination would not reasonably be expected to succeed nor would it contain all elements of Applicants' compositions.

Based on the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejections of Claims 1-4, 8-29, 31-43, and 47-50 over Evans in view of Lochhead, Grollier, Pisson, Klein, and Kim.

5. Claims 1-4, 8-29, 31-43, and 47-50

Claims 1-4, 8-29, 31-43, and 47-50 were again rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over Pisson in view of Lochhead in further view of Grollier, Kaplan, Klein, and Kim. These rejections are respectfully traversed.

The deficiencies of Pisson, Lochhead, Grollier, Kaplan, Klein, and Kim are detailed above. Notably, the compositions of Pisson contain three essential elements which are lacking in the cited publications, making impermissible such a combination. Moreover, the fields of these publications are varied, and thus one of skill in the art would not call upon them for guidance. Finally, Applicants' invention may not be used as a template for assembling an invention. Applicants maintain that the Examiner has not made out, and cannot make out, a *prima facie* case of obviousness. Instead, of select elements of

Applicants' invention have merely been identified in the cited publications. This is insufficient to negate patentability.

Based on the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejections against Claims 1-4, 8-29, 31-43, and 47-50 over Pisson in view of Lochhead, Grollier, Kaplan, Klein, and Kim.

6. Rebuttal to Examiner's "Response to 103 Arguments"

All of the pending 35 U.S.C. § 103 rejections require a combination of Lochhead with Grollier. The Examiner now admits that in making the instant rejections, she has merely "incorporated an active agent soluble in an oil phase of Grollier into the oil phase of Lochhead." *See Final Official Action, Page 12.* This admission is evidence that the Examiner has used Applicants' invention as a blueprint and has simply reconstructed Applicants' invention from bits and pieces of the cited publications. *See Interconnect Planning Corp. v. Feil*, 774 F.2d 1132 (Fed. Cir. 1985). The Examiner has entered into the "tempting but forbidden zone of hindsight." *See In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999).

Before the Examiner may "incorporate[] an active agent soluble in an oil phase of Grollier into the oil phase of Lochhead," she must first explain why one of skill, **prior to Applicants' invention**, would have selected these two publications from the universe of publications. *See Dembiczak* ("Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field").

Applicants maintain that this FIRST step may not successfully be undertaken, as there is nothing prompting one of skill to select these two publications and because even if he did so, he would recognize immediately that Lochhead and Grollier are incompatible (and, thus, undoing any possible prompt of combination!). *See discussion above.*

Therefore, one of ordinary skill would proceed no further.

Even assuming, for the sake of argument, that the cited publications were selected and modified as suggested, **Applicants also reiterate that the cited publications fail to disclose each and every element of Applicants' invention** — a showing essential to a successful obviousness determination. *See MPEP § 2142.* The publications' failure to disclose each and every element of Applicants' invention is a second, dispositive flaw in the pending rejection.

Finally, the Examiner states that Applicants' have argued against the cited publications individually. *See Final Official Action, Page 13.* This is not correct. Applicants have set forth the required steps for a proper 35 U.S.C. § 103 analysis. *See Pages 12-13 of Applicants' Reply filed September 18, 2002; see also Pages 21-22, Supra.* A proper analysis requires that an Examiner explain why one would have been motivated to select, modify, and combine the publications as he suggests. Applicants noted in detail that this requirement has not been met. As a second argument against the pending rejections, Applicants also noted that a proper analysis requires that the cited publications contain all of the claimed elements. In addition to presenting the generic flaws associated with the pending rejections, Applicants noted specific flaws within each publication. Applicants have not argued against the cited publications individually. Applicants have argued against

the totally of the rejections, and have simply coupled additional, supporting evidence from each publication to their argument.

CONCLUSION

Applicants maintain that in light of the discussions held at the Interview, the foregoing amendments and/or foregoing arguments have overcome all outstanding rejections. Accordingly, a Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this response, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,
BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____


Erin M. Dunston
Registration No. 51,147

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: April 15, 2003